IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

GWYNETH GILBERT and MICHAEL MARTE, on behalf of themselves and the Putative Class, Plaintiffs, v. LANDS' END, INC., Defendant.	Civil Action No. 3:19-cv-00823-jdp
STEPHANIE ANDREWS, et al on behalf of themselves and all others similarly situated, Plaintiffs, v. LANDS' END, INC. and LANDS' END OUTFITTERS, INC. Defendants.	Civil Action No. 3:19-cv-01066-jdp

DEFENDANT LANDS' END INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF MICHAEL FREEMAN, PH.D.

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I. INTRODUCTION

Defendant Lands' End, Inc. ("Lands' End") moves to exclude Plaintiffs' expert Dr. Michael Freeman's opinions and testimony on the grounds that Dr. Freeman's forensic medicine and epidemiology opinions are speculative and unempirical and do not reflect the application of any relevant expertise, unbiased data, or reliable scientific methodology.

Dr. Freeman is an epidemiologist and professional witness who opined that the Lands' End uniforms could and did cause Plaintiffs' health symptoms. Dr. Freeman's determination that the Lands' End uniform caused Plaintiffs' health symptoms relies entirely on Plaintiffs' self-reported answers to questionnaires completed in the course of this litigation. Dr. Freeman did not review any medical records despite Plaintiffs' counsel having those records in hand, did not speak with any of the Plaintiffs, and he did not in any way confirm that the information in the questionnaires was accurate, despite the plain potential for biases in responses prepared after Plaintiffs were parties to this lawsuit.

Using those unreliable questionnaire responses, Dr. Freeman purported to determine general causation based on a modified version of a well-known epidemiological tool: the Bradford Hill criteria. But Dr. Freeman did not first establish that the Bradford Hill criteria could properly be applied to the facts he assessed. Further, Dr. Freeman did not explain why he modified the Bradford Hill criteria, or cite any scientific or peer-reviewed basis for doing so. Because Dr. Freeman's modified Bradford Hill criteria left out crucial elements of the traditional Bradford Hill criteria and used unreliable data (the questionnaires), Dr. Freeman's approach is not competent scientific evidence to establish causation.

Again using the questionnaire responses, Dr. Freeman also purported to determine for each of the Plaintiffs whether it was probable that the Lands' End uniform caused each of the Plaintiffs' myriad health symptoms. For his specific causation analysis, Dr. Freeman used an assessment tool

(the Naranjo scale) that is meant to be used only in the context of assessing adverse drug reactions. As with the Bradford Hill criteria, Dr. Freeman modified that assessment tool without any scientific or peer-reviewed basis to do so. Moreover, he employed his modified scale arbitrarily—with a thumb on the scale of finding probable causation—so as to conclude that a higher number of Plaintiffs' health symptoms were probably caused by the Lands' End uniform. But Dr. Freeman's opinions and methodology—both as to general and specific causation—must be excluded in their entirety because they fall short of the requirements of Federal Rule of Evidence 702 and *Daubert* at every step.

Finally, while Dr. Freeman has an advanced degree in epidemiology, he has never studied or published on textiles, airlines, or environmental toxicology, is not a medical doctor, and has conducted no independent epidemiological study of the relationship between the Lands' End uniforms and Plaintiffs' alleged health symptoms (nor does he cite to any peer-reviewed epidemiological or toxicological studies on the chemicals he cites or the alleged health symptoms). Dr. Freeman's flawed opinions are best explained as those of a professional expert witness operating under a tight deadline, not a learned academic researcher or scientist, and should be excluded in their entirety.

II. BACKGROUND

Plaintiffs in this matter are 603 Delta Air Lines, Inc. ("Delta") employees who claim that various garments in their work uniform line, manufactured by Lands' End, caused an assortment of ailments, such as rashes, itching, skin irritation, blisters, hair loss, reactive airway disease, asthma, lung congestion, shortness of breath, breathing difficulties, dyspnea, excess coughing, nose congestion, sore throat, trouble swallowing, ringing in ears, vocal cord dysfunction, sinus irritations, swollen glands, gum bleeding, burning eyes, watery eyes, fatigue, insomnia, anxiety, emotional distress, fuzzy memory, blurred vision, muscle weakness, joint swelling, joint pain,

tingling in limbs, tremors, headaches, dizziness, stomach pain, nausea, diarrhea, kidney pain, bloody urine, increased heart rate, and high blood pressure. Each Plaintiff complains of at least one of the listed symptoms—no Plaintiff complains of all listed symptoms. The overwhelming majority of the 64,000 Delta employees who wore the uniforms never complained of any health effects from the uniform.

A. Dr. Freeman's Qualifications

Dr. Freeman is an epidemiologist who has training as a "medical scientist." Dkt. No. 173, Expert Report of Michael Freeman, Ph.D. ("Freeman Report") at 2. Dr. Freeman is not a medical clinician and he is neither licensed as a medical doctor in the United States nor does he perform diagnoses or treatment on patients. Although Dr. Freeman has taken classes in forensic toxicology, he does not practice in forensic toxicology and does not consider himself a toxicologist. Dkt No. 169, Dep. of Michael Freeman, February 11, 2021 ("Freeman Dep.") at 20:6–20, 31:15–17. Dr. Freeman has no prior experience with textiles or assessing physical symptoms allegedly caused by exposure to chemicals in textiles. Freeman Dep. at 30:12–15, 45:2–18.

The vast majority of Dr. Freeman's time is spent on his "forensic consulting" practice, which includes his work as an expert witness, for which he earns $900,000-$1,000,000 per year. Freeman Dep. at 28:10–19 ("70 [percent] forensic consulting, 30 percent academic and somewhere in there I fit in research unrelated to the two."), 35:10–36:3 ("I typically say average over the past five years it's around 900,000 to a million dollars per year."). Dr. Freeman has provided testimony in at least 350 trials and at least 900 depositions. Freeman Dep. at 39:9–19. Dr. Freeman testified that about half of the civil work he does relates to trauma and traffic accidents, a quarter of his work relates to medical negligence, and the remaining 25% of his civil consulting work is a "potpourri." Freeman Dep. at 41:15–42:1.

B. Dr. Freeman's Report

In his report, Dr. Freeman offers opinions on both general and specific causation. He finds that "to a reasonable degree of medical and scientific probability," the Lands' End uniform was both capable of causing and was "the most likely cause of new health problems reported by Delta Airlines [sic] employees[.]" Freeman Report at 24. Dr. Freeman's conclusions are based on his review of two sets of data: (1) the results of certain chemical and heavy metal testing of the Lands' End uniforms that was commissioned by Plaintiffs' counsel and (2) questionnaire responses prepared by Plaintiffs during the course of this litigation in which Plaintiffs self-reported their health symptoms.[1] Dr. Freeman purports to conduct two analyses using the data he compiled from the selected testing reports and questionnaire responses: a Bradford Hill analysis to show general causation and a Naranjo Scale analysis to show specific causation.

Dr. Freeman asserts that his Bradford Hill analysis shows, based on a small number of testing reports and responses to questionnaires prepared for purposes of this litigation, that the Lands' End uniforms were capable of causing all of Plaintiffs' alleged health symptoms. As explained below, without providing scientific support for his modifications, Dr. Freeman uses his own, modified version of the Bradford Hill criteria, which uses only three criteria of the traditional nine Bradford Hill criteria. In his causation analysis, Dr. Freeman thus only attempts to address plausibility, temporality, and alternative causes (but, as explained in Section IV(A)(3)(c), *infra*, Dr. Freeman actually fails to consider alternative causes). Freeman Report at 14-21. In so doing, he neglects to address seven of the nine Bradford Hill criteria: Strength, Consistency, Specificity, Biological gradient, Coherence, Experiment, and Analogy.

[1] The questionnaire was drafted by defense counsel as an alternative to initial disclosures as a means of gathering information about this case, not as a means of assessing the validity of medical or scientific data.

Again using only the litigation questionnaires to conduct an again modified version of a causal assessment tool—the Naranjo Scale—Dr. Freeman found that "for the 468 plaintiffs listed in Appendix III . . . their symptoms and complaints meet the legal standard of being causally related to their exposure to the Lands' End uniforms on a more probable than not basis." Freeman Report at 25. It is important to note, though, that of the 468 Plaintiffs for whom Dr. Freeman found a "probable" causal relationship, only 276 still remain as named Plaintiffs in this matter. Dr. Freeman describes the 10-part Naranjo scale as "a widely used algorithm designed to determine the likelihood of whether an adverse drug reaction is, in fact, due to the drug rather than other factors." Freeman Report at 15. As Dr. Freeman himself states, the Naranjo algorithm was designed for the limited purpose of assessing adverse drug reactions. But, for his analysis, Dr. Freeman modified the Naranjo scale to apply it to textiles. Dr. Freeman offers no basis or support for his modifications or application of the Naranjo scale beyond the adverse drug reaction context, either in published literature, case law, or accepted practice.

III. LEGAL STANDARD

Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579 (1993), govern the admissibility of expert testimony in federal courts, even when jurisdiction rests on diversity. *See Lewis v. CITGO Petroleum Corp*., 561 F.3d 698, 705 (7th Cir. 2009); *Stutzman v. CRST, Inc.*, 997 F.2d 291, 295 (7th Cir. 1993). Whether expert testimony is admissible depends on: "[1] whether the expert is qualified, [2] whether his methodology is scientifically reliable, and [3] whether the proposed testimony 'will help the trier of fact to understand the evidence or to determine a fact in issue.'" *United States v. Truitt*, 938 F.3d 885, 889 (7th Cir. 2019) (quoting Fed. R. Evid. 702). The proponent of the expert testimony must establish these requirements by a preponderance of the evidence. *Lewis*, 561 F.3d at 705. *Daubert* requires the district court to

perform the role of gatekeeper and to "ensure the reliability and relevancy of expert testimony." *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 607 (7th Cir. 2006) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)).

To be reliable, an expert's opinion must be subjected to the "scientific method" and cannot be the product of "subjective belief or unsupported speculation." *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002). "*Daubert* la[ys] out four factors by which courts can evaluate the reliability of expert testimony: (1) whether the expert's conclusions are falsifiable; (2) whether the expert's method has been subject to peer review; (3) whether there is a known error rate associated with the technique; and (4) whether the method is generally accepted in the relevant scientific community." *Brown v. Burlington N. Santa Fe Ry. Co*., 765 F.3d 765, 772 (7th Cir. 2014). "[T]he correct inquiry focuses not on 'the ultimate correctness of the expert's conclusions,' but rather on 'the soundness and care with which the expert arrived at her opinion.'" *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 873 (7th Cir. 2021) (quoting *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013)). An expert must rely on facts or data, not "subjective impressions." *Brown*, 765 F.3d at 772. It is "axiomatic that proper expert testimony must be derived by the scientific method." *Rains v. PPG Indus., Inc.*, 361 F. Supp. 2d 829, 833 (S.D. Ill. 2004) (quoting *Clark v. Takata Corp.*, 192 F.3d 750, 756 (7th Cir. 1999)).

IV. ARGUMENT

A. Dr. Freeman's General Causation Opinions Do Not Satisfy *Daubert*.

To support his general causation analysis, Dr. Freeman purports to use the Bradford Hill methodology. But Dr. Freeman (1) fails to show why the Bradford Hill methodology properly applies to his analysis here, (2) applies his own untested version of the Bradford Hill methodology that skips critical steps, and (3) uses unreliable data and misinterprets other data in assessing plausibility, temporality, and alternative causation. For those reasons, Dr. Freeman's general

causation analysis relies on unreliable methodology and must be excluded under Federal Rule of Evidence 702 and *Daubert*. *See Chapman*, 297 F.3d at 687 ("The purpose of the *Daubert* standard is to ensure that any admitted scientific evidence is reliable; that is, well-grounded in methods and procedures of science.") (citation omitted). Without any academic support for doing so, Dr. Freeman's Bradford Hill analysis deviates so significantly from a true Bradford Hill assessment that it must be excluded.

1. The Bradford Hill Analysis Cannot Be Used Without First Making a Threshold Showing of a Statistically Significant Association Between the Uniforms and Plaintiffs' Symptoms, Which Dr. Freeman Failed to Do.

The nine-part Bradford Hill criteria can be used in litigation "to assess whether a statistically-significant association between two variables actually reflects a causal relationship." *Rutz v. Novartis Pharms. Corp.*, No. 12-CV-0026-MJR, 2012 WL 12842794, at *10 (S.D. Ill. Dec. 7, 2012). But the Bradford Hill criteria can be used only to assess general causation *after* a statistically significant association has first been established, normally through analytic epidemiological studies. *See* Decl. of U. Gwyn Williams in Support of Lands' End, Inc.'s Mot. to Exclude the Opinions of Michael Freeman, Ph.D. ("Williams Decl."), Ex. A, Austin Bradford Hill, *The Environment and Disease: Association or Causation?,* 58 PROC. ROYAL SOC'Y MED. 295 (1965). Although Dr. Freeman's report is filled with (error-riddled) charts compiling the various testing reports and biased questionnaire data, Dr. Freeman testified that he was not offering an opinion that there was a statistically significant dose-response relationship between the Lands' End uniforms and Plaintiffs' health symptoms. Freeman Dep. at 176:9–15. Dr. Freeman thus ignores that Bradford Hill applies only when an association has been established as "perfectly clear cut and beyond what we could care to attribute to the play of chance." Bradford Hill, *supra,* at 295; *see also Dunn v. Sandoz Pharms. Corp*., 275 F. Supp. 2d 672, 678 (M.D.N.C. 2003) ("Bradford

Hill criteria is a method for determining whether the results of an epidemiological study can be said to demonstrate causation and not a method for testing an unproven hypothesis.").

Dr. Freeman did not make a threshold showing of a statistical association between *any* of the Lands' End uniform items and *any* of the Plaintiffs' alleged health symptoms. The only link that Dr. Freeman draws between the Lands' End uniforms and Plaintiffs' health symptoms as a whole is "the commonsense explanation for the plaintiffs' health problems is their exposure to the new uniforms." Freeman Report at 16. "Commonsense" is not science—it is baseless speculation. Not only does "commonsense" not show the statistically significant association needed to proceed to a Bradford Hill analysis, but when an expert relies on "his belief and assumption without any scientific testing data or supporting research material[,]" his testimony must be excluded. *Clark*, 192 F.3d at 757 (affirming exclusion of expert where "[the expert's] unequivocal testimony clearly demonstrates that he has not proven this allegation; rather, he has *assumed* it to be true") (emphasis in original); *see also Korte v. Exxonmobil Coal USA, Inc.*, 164 F. App'x 553, 557 (7th Cir. 2006) (affirming exclusion of expert who "premised his opinion on [an] assumption . . . and formed his opinion without sufficient scientific evidence confirming the validity of this premise"); *Ashley v. Schneider Nat'l Carriers, Inc*., Nos. 12-cv-8309, 13-cv-3042, 2016 WL 3125056, at *14 (N.D. Ill. June 3, 2016) ("[T]here would be a substantial risk of misleading the jury if an otherwise credible expert were to opine on [an] issue without demonstrating a scientific basis for doing so."). Dr. Freeman's "subjective experience and untestable assumptions" cannot form the basis for his expert testimony. *Brown*, 765 F.3d at 771; *Daubert*, 509 U.S. at 589–90 ("The subject of an expert's testimony must be 'scientific . . . knowledge.' . . . [T]he word 'knowledge' connotes more than subjective belief or unsupported speculation.") (citing Fed. R. Evid. 702).

Because Dr. Freeman bypassed the crucial gatekeeping inquiry before embarking on his Bradford Hill analysis, his Bradford Hill analysis must be excluded. *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg*., *Sales Practices & Prods. Liab. Litig*., 174 F. Supp. 3d 911, 925–26 (D.S.C. 2016) ("Courts exclude expert testimony that attempts to start at step two, applying the Bradford Hill criteria without adequate evidence of an association."); *Mathews v. Novartis Pharms. Corp*., No. 3:12-CV-314, 2013 WL 5780415, at *27 (S.D. Ohio Oct. 25, 2013) ("Unless there is a statistically significant association between the drug and the disease, the Bradford-Hill analysis to determine causation is inapplicable."); *Soldo v. Sandoz Pharms. Corp*., 244 F. Supp. 2d 434, 569 (W.D. Pa. 2003) (finding that the Bradford Hill analysis was unwarranted because there were no analytic epidemiological studies showing a statistically significant association); Federal Judicial Center, *Reference Manual on Scientific Evidence* 598–99 & n.141 (3d ed. 2011), https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf ("*Reference Manual on Scientific Evidence*") (emphasizing that the Bradford Hill factors "are employed only *after* a study finds an association to determine whether that association reflects a true causal relationship." (emphasis in original)).

2. The Court Should Exclude Dr. Freeman's Testimony as His Three-Part Bradford Hill Methodology Is Unreliable and Untested.

Setting aside the fact that the Bradford Hill analysis is inapplicable without the threshold showing of a statistically significant association, were a Bradford Hill analysis appropriate, such an analysis requires competent consideration of all ***nine*** Bradford Hill criteria. In his report, however, not only does Dr. Freeman bypass the threshold assessment of statistical significance, but he asserts that the Bradford Hill criteria can be "distilled into a 3-step approach" that considers only plausibility, temporality, and alternative causation. Freeman Report at 14–15.

Dr. Freeman's three-part Bradford Hill analysis has not been accepted by the scientific community. Indeed, the third element of Dr. Freeman's three-part analysis ("alternative cause") is not even one of the nine Bradford Hill guidelines. *See* Dkt. No. 178, Expert Report of Marion J. Fedoruk, MD, CIH, DABT, FACMT, FACOEM ("Fedoruk Report") at 30. Further, Dr. Freeman ignores completely seven of the Bradford Hill factors: Strength, Consistency, Specificity, Biological gradient, Coherence, Experiment, and Analogy. *See id.* at 32. Dr. Freeman's failure to assess biological gradient (essentially dose-response) is particularly glaring because the Federal Judicial Center, *Reference Manual on Scientific Evidence*, describes all ***nine*** Bradford Hill criteria in its section on using epidemiology to evaluate general causation, stressing that "[g]enerally, higher exposures should increase the incidence (or severity) of disease." *See* Fedoruk Report at 32 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence*, 2011). Despite claiming that his "methods" "are consistent" with those outlined in the *Reference Manual on Scientific Evidence*, Freeman Report at 1, Dr. Freeman never provides evidence to demonstrate a biological gradient. Similarly, Dr. Freeman fails to address consistency, despite the admonishment from the National Research Council that "[c]onsistency" in research findings "is an important factor in making a judgment about causation." *See* Fedoruk Report at 33 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence*, 2011). Although one or more of the Bradford Hill factors may be absent where a causal relationship exists, *Rains*, 361 F. Supp. 2d at 835 n.4, the only support Dr. Freeman cites in favor of using his three-factor test over the accepted nine-

factor test are two articles he authored on the topic: one a non-peer reviewed guest editorial published in *Orthopedics* journal and the second an article about motor vehicle crashes.[2]

An "expert['s] work is admissible only to the extent it is reasoned, uses the methods of the discipline, and is founded on data." *Bourelle v. Crown Equip. Corp*., 220 F.3d 532, 539 (7th Cir. 2000). Dr. Freeman flouted the requirements of the Bradford Hill Analysis: he ignored the necessary threshold analysis and arbitrarily manipulated the nine-part test in order to apply an unsupported, untested, and unproven three-part analysis. While Dr. Freeman purports to use a reputable methodology, he casts aside most of the actual Bradford Hill criteria. *Brown,* 765 F.3d. at 773 ("[A]n expert must do more than just state that she is applying a respected methodology; she must follow through with it."). Dr. Freeman could have conducted a true Bradford Hill assessment, but chose to use his own method, which has not been widely accepted by the scientific community as a valid method itself or as a valid replacement to the Bradford Hill nine-part analysis. This Court should exclude Dr. Freeman's Bradford Hill analysis as it falls short of *Daubert* at every step: Dr. Freeman's watered-down Bradford Hill methodology has not been

[2] The differences between the alleged exposure and injuries at issue to those that arise and how they arise from a motor vehicle accident are obvious. The only case Dr. Freeman cites in support of his three-part methodology, *Etherton v. Owners Ins. Co.*, a case about a motor vehicle crash, found that the three-part methodology was valid because (1) as to plausibility, the expert showed "the medical literature is rampant with evidence that rear-end-impact motor vehicle crashes can lead to lumbar spine injury" and relied on his work as an instructor at the Spine Research Institute; (2) as to temporality, the expert "examined [Plaintiff's] medical records to determine whether the injury coincided with the collision"; and (3) as to alternative causes, the expert "testified that he ruled out alternative explanations based on '[his] history with [Plaintiff], [his] findings on physical examination, the diagnostic testing that [he] had available to [him] through the course of [Plaintiff's] care, and the lack of predated records[.]'" 829 F.3d 1209, 1220–22 (10th Cir. 2016). The expert further "considered 'anything else that would be a more likely cause or a better alternative cause for the condition [Plaintiff] was presenting for.'" *Id.* Dr. Freeman's analysis falls short at every step: he cites no medical literature showing that the Lands' End uniforms can cause all (or even any) of Plaintiffs' alleged symptoms; he did not examine medical records or conduct physical examinations for any Plaintiffs; and he did not consider *any* alternative causes.

tested, is not supported by the literature, has no known error rate, and has been used only in the limited context of motor vehicles accidents. *See Daubert*, 509 U.S. at 594 ("[A] known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism.") (internal quotation marks and citation omitted).

3. Dr. Freeman's Bradford Hill Analysis Fails to Reliably Establish That the Lands' End Uniforms Could Cause Plaintiffs' Alleged Injuries.

Even if Dr. Freeman did not ignore the prima facie requirements for using the Bradford Hill analysis and his modified three-part analysis were reliable, his application of his three supposed Bradford Hill criteria—plausibility, temporality, and alternative causation—is fatally flawed. Because Dr. Freeman fails to establish that his Bradford Hill analysis is well-grounded in reliable data, methods, and procedures of science, his testimony does not satisfy the *Daubert* standard. *See Chapman*, 297 F.3d at 687.

a. Dr. Freeman's Plausibility Analysis Is Not Methodologically Sound Because It Relies on Unreliable Data.

Under the Bradford Hill criteria, the plausibility analysis should rest on currently available scientific evidence. *See* Fedoruk Report at 29. Instead, Dr. Freeman's plausibility analysis relies entirely on (1) a smoke-and-mirrors analysis of a carefully curated set of heavy metal and chemical testing reports that Plaintiffs' counsel commissioned and (2) questionnaires that were completed by the Plaintiffs *during this litigation*. Under Federal Rule of Evidence 702, such improper data cannot be used to support expert testimony.

(1) Dr. Freeman Does Not Establish That Any Lands' End Garment Contained Any Substance at Levels That Could Plausibly Cause Plaintiffs' Injuries.

Dr. Freeman's plausibility "analysis" does not provide any competent scientific evidence that the uniform garments could cause Plaintiffs' alleged symptoms. Dr. Freeman's plausibility analysis rests on two premises that he never establishes through reliable methodology: (1) that all

of the Lands' End uniform garments contained certain substances, and (2) that the amounts of those substances in the Lands' End uniform garments are known in scientific or medical literature to be capable of causing Plaintiffs' alleged injuries. Instead of analyzing evidence and scientific or medical literature, Dr. Freeman apparently assumes that any substance at any level more than "[textile] industry accepted safe levels" necessarily could cause the symptoms Plaintiffs allege. *See* Freeman Report at 19–20 ("[E]xposure to chemicals in dyes and finishes in the new Delta uniforms manufactured by Lands' End very plausibly resulted in the health problems [Plaintiffs] experienced.") (emphasis omitted); Freeman Report at 5 ("Tests of the uniforms found the presence of chemicals and heavy metals more than industry accepted safe levels for garments."). This supposition falls short of scientific standards in the field of toxicology, because Dr. Freeman never states what level of exposure to such substances would be necessary to cause the Plaintiffs' varied alleged conditions.[3]

More problematic, Dr. Freeman undertakes no analysis to support his supposition that the Lands' End uniforms are plausibly related to Plaintiffs' health symptoms; nor could he credibly

[3] Relatedly, and as discussed in Lands' End's Motion to Exclude the Opinions of Dr. Fred Apple, without information on exposure or dose, Dr. Freeman cannot purport to link Plaintiff's alleged health symptoms to the Lands' End uniforms. *See Wintz ex rel. Wintz v. Northrop Corp.*, 110 F.3d. 508, 513–14 (7th Cir. 1997) (finding "experience, knowledge, and methodology simply were not sufficient to permit [expert] to offer an expert opinion" where the expert had insufficient information about both the plaintiff and her alleged exposure to bromide and expert had not examined or spoken with Plaintiff, had not reviewed Plaintiff's medical records, and did not know the specifics of Plaintiff's alleged exposure to bromide). Dr. Freeman also cites to OEKO-TEX limit values, which are one set of standards for textiles promulgated by a private organization, but does not provide any evidence from epidemiological or toxicological studies showing what levels of those chemicals can cause health problems, if any. Dr. Freeman does not establish how or why OEKO-TEX chooses limit values, and his reference to them is therefore useless. *See Cunningham v. Masterwear Corp.*, 569 F.3d 673, 675 (7th Cir. 2009) (explaining that regulatory limits can be set for a variety of reasons, and are insufficient, on their own, to establish causation for any particular symptom).

do so. Instead, Dr. Freeman asserts "[t]here is abundant evidence that the uniforms were transferring dye and dye-related chemicals and heavy metals to the bodies of the Delta employees who wore them." Freeman Report at 16. Yet Dr. Freeman cites no evidence that the dye transfer (if any) necessarily caused transfer of the substances Dr. Freeman asserts could cause Plaintiffs' alleged injuries. First, even if dye transfer did include those substances, Dr. Freeman (nor any other expert disclosed by Plaintiffs) never establishes which substances are from the dye, and which are from other sources. Second, even if the dye transferred certain substances, this would only account for dermal exposure, but Dr. Freeman fails to assess which alleged ailments could be caused by dermal exposure as opposed to a different route of exposure, such as inhalation. Third, Dr. Freeman does not attempt to connect the number of Plaintiffs reporting dye transfer to skin with the number of Plaintiffs reporting physical ailments. In fact, the groups do not correlate one-to-one.[4] "[A]n expert opinion that lacks a proper factual foundation is little more than 'unscientific speculation offered by a genuine scientist,' and thus is both unreliable and inadmissible." *Comer v. Am. Elec. Power*, 63 F. Supp. 2d 927, 934 (N.D. Ind. 1999) (quoting *Rosen v. Ciba–Geigy Corp*., 78 F.3d 316, 318 (7th Cir. 1996)).[5] Despite his lack of expertise in environmental toxicology, Dr. Freeman did not attempt to support his premise by reviewing toxicological analyses from a toxicologist on whom he could rely. Instead, Dr. Freeman purported to review garment test results provided to him by Plaintiffs' counsel, *see* Freeman Dep. at 72:17–73:1, while ignoring those garment testing results that were not consistent with his supposition, such as Bureau Veritas test results which

[4] Per the questionnaire responses that Dr. Freeman relies upon so heavily, nearly every Plaintiff is alleging physical ailments, while only approximately one third are claiming property damage from crocking.

[5] For the avoidance of doubt, Lands' End does not concede that Dr. Freeman can be considered a "genuine scientist."

found no detectable extractable formaldehyde. *See* Fedoruk Report at 20-21 ("Plaintiffs' experts largely ignore inconsistent test results . . . and gaps in testing.").

More so, Dr. Freeman misinterpreted the selected garment testing results he relied upon because Dr. Freeman used the wrong benchmarks for measuring industry standard limits. Instead, Dr. Freeman interpreted test results that measured *total* values and compared them with industry standards for *extractable* values. *See* Freeman Report at 6 (Table 2). Conflating total levels with extractable levels lacks scientific validity. *See* Fedoruk Report at 21-23. Thus, to the extent Dr. Freeman arguably employed a scientific method to reach his conclusion on plausibility, his errors in applying that methodology render his analysis unreliable. Although an expert can rely on testing done by a third party, he must have some basis for understanding that testing and validating its reliability. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 789 (7th Cir. 2017) ("[a]n expert is not entitled to testify to opinions that rely on the opinion of another expert, simply because the other is an expert") (quoting *Mooring Capital Fund, LLC v. Knight*, 388 F. App'x 814, 820 (10th Cir. 2010); *see also Sanchelima Int'l, Inc. v. Walker Stainless Equip. Co., LLC*, No. 16-CV-644-JDP, 2018 WL 1401195, at *2 (W.D. Wis. Mar. 19, 2018), *aff'd*, 920 F.3d 1141 (7th Cir. 2019) (noting that the Federal Rules of Evidence "do[] not necessarily allow a witness to rely on the methodology of another expert['s]" report where the underlying report "does not at all explain the underlying data or methods used to reach its [] finding"). Dr. Freeman does neither. In fact, proper comparison undercuts Dr. Freeman's plausibility analysis. When Bureau Veritas and Intertox conducted the proper comparison of extractable values and limits on extractable values, none of the tests showed levels that exceeded industry standards. *See* Freeman Dep. at 151:7–152:6, 159:11–25; Fedoruk Report at 24. Further, even if Dr. Freeman considered the proper limits in his analysis, he does not address that certain of the garment testing results involved testing worn

garments, which fail to control for the environmental exposures to substances that are common in daily life. *See* Fedoruk Report at 20. This, too, renders Dr. Freeman's analysis unreliable.

Finally, Dr. Freeman testified that the dose of exposure matters in terms of potential human reaction to a substance, *see* Freeman Dep. at 95:19–22, 166:2-167–12, but he took no steps to measure dose as a means to determine the plausibility of the actual exposure (if any) causing the alleged reaction. Dr. Freeman does not attempt to analyze what dose of any given substance a wearer could be exposed to for any given garment in the approximately 100-item Delta Uniform line,[6] though Dr. Freeman admits that the specific garment is relevant to the analysis. *See* Freeman Dep. at 97:1–14, 166:2–167:12. In fact, courts in this Circuit routinely exclude exposure-based expert opinions that fail to account the amount of exposure. *See Higgins v. Koch Dev. Corp.*, No. 3:11-cv-81-RLY-WGH, 2013 WL 6238650, at *9 (S.D. Ind. Dec. 3, 2013) (expert's opinion that did not discuss the extent of exposure and failed to rely on medical literature was "not [a] sufficient methodology for proving causation"); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *8 (S.D. Ind. Apr. 19, 2007) (excluding expert opinion that made no determination as to the type of exposure and whether it was enough to cause the alleged symptoms). At most, Dr. Freeman asserts that the self-reported "frequency" (measured in days and not hours) with which a Plaintiff wore the uniform "demonstrated a dose-response relationship." Freeman Report at 20. Dr. Freeman's "frequency" "analysis" is nothing more than basic arithmetic from Plaintiffs' own unvalidated, biased self-reporting, and he does not attempt

[6] Dr. Freeman, by his own admission, does not have "the ability to say this item specifically is the one that caused – you know, X number of symptoms." Freeman Dep. at 92:20–23; *see Aurand v. Norfolk Southern Ry. Co.*, 802 F. Supp. 2d 950, 955 (N.D. Ind. 2011) (excluding expert toxicologist in part because his report, which listed a number of chemicals, did not "specifically identify the carcinogenic chemicals to which plaintiffs were exposed, nor do that conclusions state which agent or agents caused the plaintiffs' cancers").

to show statistical significance in his "finding." *See id.*; Freeman Dep. at 175:21–25 ("Q: But you did not do that [statistical significance] analysis for the figures that we were just discussing [] on dose-response relationship, right? A: I did not.").

Rife with mistakes and built upon unreliable data, Dr. Freeman's "method" for assessing whether the Plaintiffs were plausibly exposed to toxins at levels that could cause their alleged symptoms is not "generally accepted in the relevant scientific community." *Brown*, 765 F.3d at 772. Instead, Dr. Freeman offers only supposition, which will not assist the trier of fact. For those reasons, the Court should exclude Dr. Freeman's opinion on general causation in its entirety.

(2) Dr. Freeman's Assessment of Plaintiffs' Claimed Injuries is Unreliable Evidence of a Plausible Causal Relationship.

For his Bradford Hill plausibility analysis, Dr. Freeman also errs as his only source of information on Plaintiffs' alleged health symptoms are Plaintiffs' own questionnaire responses completed during the course of this litigation.[7] *See* Freeman Dep. at 61:20–23 ("[M]y analysis is limited to as far as individuals just what I've gleaned from the questionnaires."). Plaintiffs were asked to self-report which uniform items they wore, whether they wore each item "occasionally, weekly, or daily," all health symptoms they claimed were a result of the uniform, whether they experienced any of those symptoms prior to when they first wore the uniform, and to list any respiratory, cardiovascular, or dermatological illness with which they have been diagnosed that

[7] In addition to the litigation questionnaires, Dr. Freeman found "prior reports of garment-related illness outbreaks in the airline industry." Freeman Report at 16. The single epidemiological study he cites pertains to an Alaska Airline uniform, which was manufactured by a company other than Lands' End, with different performance finishes, and different dyes (none of which Dr. Freeman accounts for). Dr. Freeman admits the study participants were not consistent over the full time frame, a fact which he conceded was not "ideal," Freeman Dep. at 118:1–19, but he does not address any of the potential additional limitations of the cited study. *Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1032 (S.D. Ill. 2001) ("If an epidemiologist finds any association (either positive or negative), he then scrutinizes the results in [the] particular study to determine whether that association indicates a causal relationship or is due to chance, error or bias.").

they do not claim are attributable to the uniform. Plaintiffs were not asked as a part of that process to provide medical records or evidence to validate the information in their responses.

To put it bluntly, the questionnaires are Dr. Freeman's exclusive source of information on Plaintiffs' alleged health symptoms and they were completed by a population with a financial stake in the outcome of this litigation. *See* Freeman Dep. at 188:20–189:1 ("Q. Okay. So you would agree with me that in that case everybody who filled out the questionnaire had some potential financial interest in answering that they experienced medical symptoms after they started wearing the uniform, right? A. Yeah.").[8] Moreover, Dr. Freeman did not review *any* information from *any* Delta employee other than those involved in this litigation. *See* Freeman Dep. at 99:7–16 ("Q. So you had information about self-reported health symptoms for the people for whom you received questionnaires, right? A. Yes. Q. And you did not have any information about health issues or medical issues for any Delta employees other than that group, right? A. Not as far as I know."). In order to show general causation, "[i]n a typical epidemiologic study, an epidemiologist compares the health of people exposed to a substance to that of persons not so exposed to determine whether the exposure to the substance is associated with an increased rate of disease." *See Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1031 (S.D. Ill. 2001); *Reference Manual on Scientific Evidence* 218–19 ("A good study design compares outcomes for subjects who are exposed to some factor (the treatment group) with outcomes for other subjects who are not exposed (the control group)."). Despite his claims that his methods "are consistent with those outlined in

[8] Further discrediting Dr. Freeman's analytical methods, Dr. Freeman testified that, even if he had known the questionnaires were completed during litigation, such knowledge would not have changed his assessment. *See* Freeman Dep. at 188:1–14. Epidemiological studies that use self-reported data must account for potential bias in respondents' answers. *See Reference Manual on Scientific Evidence* 583 ("In reviewing the validity of an epidemiologic study, the epidemiologist must identify potential biases and analyze the amount or kind of error that might have been induced by the bias."). Dr. Freeman has not done so, and apparently sees no need to do so.

the *Reference Manual on Scientific Evidence*," *see* Freeman Report at 1, Dr. Freeman has no information on the incidence of the alleged symptoms—or lack of symptoms—in the approximately 63,000 uniform-wearing Delta employees who did not sue Lands' End. *See* Freeman Dep. at 101:3–9 ("If there were 64,000 Delta employees who wore some Lands' End garment, that would be your total population of people who had been potentially exposed to some triggering event, right? A. Yes."). As a result, Dr. Freeman is unable to make any conclusions about the "entire population of exposed employees," Freeman Report at 24, or to compare the incidence of Plaintiffs' alleged health symptoms to that of the entire population of individuals who wore the Lands' End uniform or even to the general population. Nonetheless, Dr. Freeman offers a general causation opinion that apparently applies to anyone who wore the Lands' End uniform. This unscientific leap does not pass muster and should be excluded under *Daubert*.

Despite the glaring concerns with relying on the questionnaires to offer a general causation opinion, to support his plausibility assessment, Dr. Freeman purported to analyze the questionnaires to assess the number of symptoms Plaintiffs' alleged were caused by the uniforms. Freeman Report at 10, 12, Table 8. Dr. Freeman's "analysis" of Plaintiffs' questionnaires is nothing more than an accounting of the number of symptoms that Plaintiffs' listed in their self-reported questionnaires and a report, based on Plaintiffs' best estimates, on the number of times per week that Plaintiffs wore *any* uniform item, as opposed to the frequency with which Plaintiffs wore *specific* uniform items. But the questionnaires are not evidence that Plaintiffs were diagnosed with any of the symptoms they alleged or even evidence that Plaintiffs actually suffered from the litany of symptoms they allege.[9] *See* Freeman Dep. at 115:21–24 ("I don't truly know whether any

[9] Dr. Freeman's excuse for basing his causation analysis on such flawed and unreliable data is that "[t]here is no ability for someone to interrogate the patient and follow-up on a complaint," Freeman Dep. at 64:7–10. That statement is false. First, Dr. Freeman could have interviewed any

of these symptoms are actually experienced because it is an individual experience like the bananas make me nauseous kind of thing."). Without medical records, Dr. Freeman had no clinical confirmation of Plaintiffs' self-reported health symptoms and no clinical information on Plaintiffs' medical history, including any underlying health conditions that could explain their claimed symptoms. *See Smith v. Ill. Dep't of Transp*., 936 F.3d 554, 558–59 (7th Cir. 2019) (upholding district court's determination to exclude expert testimony where expert did not interview plaintiff or review deposition testimony and expert "omitted a substantial set of facts from her analysis, and instead relied only on what appears to be plaintiff-curated records. [Expert's] reliance on an anemic and one-sided set of facts casts significant doubt on the soundness of her opinion, and the court did not abuse its discretion by excluding it"). Without validation (which, contrary to Dr. Freeman's assertion, Freeman Dep. at 80:13–18, can indeed be done through medical records, particularly for symptoms such as skin rash), the questionnaires cannot be used to support Dr. Freeman's general causation opinion that the Lands' End uniforms are plausibility related to Plaintiffs' alleged health symptoms. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 762 (3rd Cir. 1994) ("We do not doubt the propriety of a medical report prepared just for litigation purposes, but a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and hence should either examine the patient or review the patient's medical records simply in order to determine that a patient is ill and what illness the patient has contracted. Thus, we are satisfied that where [Plaintiffs' experts] based their conclusion as to a plaintiff's

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of the Plaintiffs at any time. Dr. Freeman chose not to do so in this case. Further, Dr. Freeman could have reviewed medical records to validate the questionnaires, but again chose not to do so, even though Dr. Freeman admits that he has not testified to specific causation in a personal injury lawsuit without having medical records. *See* Freeman Dep. at 230:4–10 ("Q. Have you ever testified to -- have you ever testified to specific causation in a personal injury lawsuit without having any medical records on the plaintiff? A. I would say that I don't have a recollection of having done so.").

symptoms solely on the plaintiff's self-report of illness in preparation for litigation, the district court acted within its discretion in excluding the testimony as based on an unreliable source of information.").

b. Dr. Freeman's Perfunctory Temporality Analysis Is Unreliable.

To support the temporality of a causal effect of chemicals in the uniforms on the Plaintiffs' claimed injuries, Dr. Freeman again cites findings from Plaintiffs' unvalidated symptom questionnaires. As discussed above, all of the questionnaire data were self-reported by Plaintiffs during and for litigation and are unreliable sources of information under Federal Rule of Evidence 702. Thus, not only is that data an invalid basis for establishing the temporal sequence of exposure to the Lands' End uniforms and the onset of symptoms but, as Dr. Freeman himself testified, the Plaintiffs' responses to the questionnaire regarding temporal sequence are frequently so vague as to render it impossible to adequately assess temporality. *See* Freeman Dep. at 183:15–184:5 ("Q. So when somebody -- and this is just the design of the questionnaire, but when somebody answers the question, what if -- what symptoms did you experience after wearing the uniform, absent more information, you have no way of knowing, right, whether that was the next day or eight months later? A. That is true other than the common sense that if you say what happened to you afterwards most people respond in a similar fashion which is to say, well, after. Do you mean ten years after? Most people would say no after, I mean yes within a matter of hours or days or whatever it is."), 201:14–23 ("[B]ecause of the way the questionnaire is worded it ends up with an ambiguous response"), 204:9–20 ("Q. As I think we just determined from looking at a few of these questionnaires, for some of them at any rate, it was difficult with the information that you had to do that nuanced and careful consideration for the temporality factor for some of these individual people, right? A. Well, there's certainly contradictory or more obscure information in some of the questionnaires some of the responses.").

It is no surprise that the questionnaires drafted by counsel for Lands' End yielded unreliable temporal data, as the questionnaires were drafted by lawyers, not scientists or doctors, and were not written or designed to control for Plaintiffs' subjective, self-reported responses. *See* Freeman. Dep. at 126:6–7 ("[a]nything that is self-reported is subjective"); *see also Muha v. Encore Receivable Mgmt., Inc.*, 516 F. Supp. 2d 959, 963 (E.D. Wis. 2007), *rev'd on other grounds*, 558 F.3d 623 (7th Cir. 2009) ("The plaintiffs' survey is unreliable and irrelevant for several important reasons. The design of the survey questions is neither scientific nor impartial. Plaintiffs' expert did not design the questions, rather plaintiffs' counsel did."). The questionnaires do not consistently provide evidence (let alone adequate evidence) of the length of time between the alleged exposure and the alleged injury, a key factor in the temporality analysis under Bradford Hill. Thus, Dr. Freeman's temporal analysis, like his plausibility analysis, is based entirely on unreliable data.

c. Dr. Freeman Entirely Ignores Alternative Causation, Rendering His Bradford Hill Analysis Unreliable.

Alternative causation is not one of the ***nine*** Bradford Hill criteria.[10] *See* Fedoruk Report at 30. Even if it were a part of the Bradford Hill analysis, Dr. Freeman makes only a passing comment that "[t]here are no apparent alternative explanations for the symptoms and injuries attributed by Delta personnel to the wearing of the new Lands' End uniforms." Freeman Report at 21. This conclusory statement does not reflect a scientific method. For example, although Dr. Freeman admits that respiratory symptoms may be more common among flight attendants than in the general population, he does not account for this in his causation analysis. Freeman Dep. at 129:8–13 ("Respiratory symptoms are something that you find relatively common – more common

[10] Although alternative causation is not one of nine Bradford Hill criteria, it is nonetheless a crucial element to assess for causation. As Dr. Freeman's specific causation analysis makes clear, it is not possible to say that Lands' End uniforms caused any of Plaintiffs' health symptoms absent ruling out potential alternative causes.

amongst folks who are in planes."). Further, Dr. Freeman does not attempt to grapple with the myriad potential causes for Plaintiffs' other alleged symptoms, such as rash, hair loss, and fatigue. "Under circumstances where symptoms may be the subject of a variety of causes it is insufficient for an expert to opine as to the cause of the symptom without some scientific basis other than his assertion of general experience." *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941, 951 (W.D. Wis. 1998) (citing *O'Conner v. Commonwealth Edison Co*., 13 F.3d 1090, 1106–07 (7th Cir. 1994)).

Because Dr. Freeman failed to explain potential alternative causes that he had considered and ruled out, his general causation opinion must be excluded. *Gopalratnam*, 877 F.3d at 787 (affirming exclusion of expert in part because he "failed to account for other possible explanations in arriving at his conclusion"); *Brown*, 765 F.3d at 774 (affirming exclusion of expert for failing to investigate and rule out any serious alternative causes); *Clark*, 192 F.3d at 757 ("An expert must substantiate his opinion; providing only an ultimate conclusion with no analysis is meaningless.") (internal quotation marks omitted).

B. The Court Should Exclude Dr. Freeman's Specific Causation Opinions as His Application of the Naranjo Scale Is Unreliable and Untested.

Dr. Freeman's misuse of epidemiological methods extends to his specific causation opinion, which he claims supports specific causation for 276 of the remaining Plaintiffs. To support his specific causation opinion, Dr. Freeman relies on the Naranjo Algorithm, otherwise known as the "Adverse Drug Reaction Probability Scale." As that name suggests, there is no support for Dr. Freeman's decision to use that scale to evaluate symptoms potentially caused by substances in textiles. Nonetheless, Dr. Freeman modified the questions in the Naranjo scale in an effort to render the analysis applicable to textiles. He then purported to assess each of the ten

questions for each Plaintiff,[11] based on the Plaintiff's questionnaire responses, and classify each Plaintiff's symptoms as "probably" or "possibly" caused by the Lands' End uniform. For those Plaintiffs for whom Dr. Freeman found a "probable" relationship, he opined that "their symptoms and complaints meet the legal standard of being causally related to their exposure to the Lands' End uniforms on a more probable than not basis." Freeman Report at 25. Dr. Freeman's Naranjo assessment, like his Bradford Hill analysis, fails to meet the *Daubert* requirements as (1) Dr. Freeman offers no support that the Naranjo scale can be used outside the context of adverse drug reactions; and (2) like his Bradford Hill analysis, Dr. Freeman's Naranjo methodology was arbitrarily designed, put a thumb on the scale in favor of finding specific causation, used unreliable data, cannot be tested, and has no known error rate.

1. The Naranjo Scale Does Not Apply Outside the Context of Adverse Drug Reactions.

The Naranjo algorithm was designed for assessing adverse drug reactions and its use has been neither tested nor deemed appropriate in the context of textiles or alleged chemical/heavy metal reactions. Further, the Naranjo scale is a classification system, not a method for assessing causation. *Rhodes v. Bayer Healthcare Pharms., Inc*., No 10-1695, 2013 WL 1289050, at *6 (W.D. La. Mar. 26, 2013) ("[T]he Naranjo algorithm/methodology appears, in actuality, to be a classification system, not a method used to determine actual causal relationships and/or causality assessments.") (citation omitted).

To support his assertion that the Naranjo scale may be applied to "adverse reactions associated with any known toxic exposure with a close temporal relationship to effects plausibly related to the exposure," Dr. Freeman cites an article entitled "Herbal hepatotoxicity: challenges

[11] As discussed below, though, Dr. Freeman actually only answered three of his ten Naranjo scale questions on an individual basis for each Plaintiff; the rest were answered in a general fashion.

and pitfalls of causality assessment methods." Freeman Report at 15. Dr. Freeman testified that he cited a paper on herbal hepatotoxicity—or herb-induced liver damage—to show that nine percent of articles on herbal hepatotoxicity use the Naranjo scale. *See* Freeman Dep. at 220:17–221:17. But Dr. Freeman does not explain how herbal hepatotoxicity is even relevant to the Plaintiffs' claims. Further, the article that Dr. Freeman cites in support of his claims actually states that "the Naranjo scale *should be excluded from use* in hepatotoxicity cases."[12]

Further, in an effort to fit a square peg into a round hole, Dr. Freeman then arbitrarily modifies the Naranjo scale to apply it to the facts at hand. Dr. Freeman cites one article that he claims supports that the Naranjo scale *can* be modified, but that source offers no support for the specific modifications Dr. Freeman made. *See* Freeman Dep. at 222:2–18 ("I did not cite to it for the fact it's used for nondrug applications. I cited to the statement that the Naranjo -- use of the Naranjo scale may include modifications or Hill criterion additions."). The article Dr. Freeman cites, however, concerns whether the modified Naranjo scale might be of use to "pharmacovigilance safety professionals when evaluating **drug-event** causality."[13] The article does not state that the Naranjo scale can be used, let alone modified for use, outside the context of drug-related causality. In fact, the study shows that the Naranjo scale is not a useful tool in the present context, where there are various performance finishes made up of various chemical additives, as the study found that the modified Naranjo scale "is not able to classify complex cases involving more than one [potential] specific causative drug."[14]

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[12] Williams Decl., Ex. B, Rolf Teschke et al., *Herbal Hepatotoxicity: Challenges and Pitfalls of Causality Assessment Methods*, 19 WORLD J GASTROENTEROL. 2864, 2876 (2013) (emphasis added).

[13] Williams Decl., Ex. C, Shaun Comfort et al., *Modified Naranjo Causality Scale for ICSRs (MONARCSi): A Decision Support Tool for Safety Scientists*, 41 DRUG SAFETY 1073, 1073 (2018) (emphasis added).

[14] *Id.* at 1083.

Nonetheless, Dr. Freeman modified the Naranjo scale in an attempt to support his desired conclusion. Dr. Freeman did not explain how he decided on the modified questions, or why the language he used should be read to align with the language in the Naranjo scale. Without such explanation, it is impossible to see how Dr. Freeman's Naranjo analysis satisfies *Daubert*, as one cannot replicate Dr. Freeman's findings without knowing the basis for his modifications. *Daubert*, 590 U.S. at 593 (quoting Karl Popper, *Conjectures and Refutations: The Growth of Scientific Knowledge* 37 (5th ed. 1989) ("[T]he criterion of the scientific status of a theory is its falsifiability, or refutability, or testability.") (emphasis deleted)).

After a diligent search, it appears the Naranjo scale has not been used in the Seventh Circuit, and Dr. Freeman's modifications have never been used outside the present litigation. The below chart reveals the clear differences between the Naranjo scale that has accepted use in the field of adverse drug reactions, and Dr. Freeman's untested scale.

Naranjo Scale[15]	**Dr. Freeman's Scale**
1. Are there previous conclusive reports *on this reaction*?	1. Are there previous conclusive reports on adverse health reactions to garments?
2. Did the adverse event appear after the suspected drug was administered?	2. Did the adverse event/ reaction appear after the exposure to the garments?
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	3. Did the adverse event/ reaction improve once the garments were no longer worn?
4. Did the adverse reaction reappear when the drug was readministered?	4. Did the adverse event/ reaction reappear after the garments were worn again?
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	5. Are there alternative causes that could have caused the same reaction?
6. Did the reaction reappear when a placebo was given?	6. Did the reaction reappear when non-Lands' End garments were worn?
7. Was the drug detected in the blood (or other fluids) in concentration known to be toxic?	7. Were toxins from the garments detected in blood or other fluids?
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	8. Was the reaction more severe when the exposure was increased?

[15] Williams Decl., Ex. D, C.A. Naranjo et al., *A Method for Estimating the Probability of Adverse Drug Reactions,* 30 CLIN. PHARMACOL. THER. 239 (1981) (emphasis added).

9. Did the patient have a similar reaction to the same or similar drugs in *any* previous experiment?	9. Did the employee have a similar reaction prior to the exposure to the new uniforms?
10. Was the adverse event confirmed by any objective evidence?	10. Was the adverse event confirmed by any objective evidence?

The differences between the actual Naranjo scale and Dr. Freeman's self-made and untested version demonstrate that Dr. Freeman's supposed "Naranjo scale" bears little resemblance to the actual published Naranjo scale, and thus is scientifically unreliable.

2. Dr. Freeman's Specific Causation Analysis Does Not Satisfy *Daubert*.

Even though the Naranjo scale is inapplicable to purported chemical exposure from textiles and Dr. Freeman had no scientific basis for modifying it in the way he did, he purports to use the litigation questionnaires to conduct a specific causation analysis.[16] In his report, Dr. Freeman claims to conduct a "Specific Causation Analysis" using the Naranjo algorithm for 908 Plaintiffs who self-reported health symptoms after wearing various uniform garments. Based on only the information in the litigation questionnaires, Dr. Freeman concludes that for "468 plaintiffs . . . their

[16] In his report, Dr. Freeman also purports to use the Naranjo scale to support his general causation analysis. Dr. Freeman answers each of his modified Naranjo questions on behalf of *all* uniform wearers and determines that, based on the Naranjo scale score for Plaintiffs as a whole, the Lands' End uniforms are "definitely related" to Plaintiffs' "adverse reactions." Freeman Report at 22–23. As an initial matter, it is apparent from the nature of the questions that they cannot be answered on behalf of hundreds of people at the same time (i.e. "Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?" and "Was the drug detected in the blood (or other fluids) in concentration known to be toxic?"). Further, the Naranjo scale is plainly not intended to be used for general causation and Dr. Freeman's general causation Naranjo analysis should be excluded accordingly. *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1357 n.144 (N.D. Fla. 2018) ("The Naranjo Scale is used in determining the causal link between a drug and an individual clinical event (*i.e.*, specific causation) . . . . As noted, the Naranjo Scale is not a general causation tool."). Lands' End has been unable to find any precedent in the Seventh Circuit (or elsewhere) recognizing the use of the Naranjo scale for general causation. In fact, Dr. Freeman himself testified that "all uses of the Naranjo scale are for specific causation." Freeman Dep. at 223:7–8. As the Naranjo scale was intended to be used for case-by-case assessments, as evident from questions that comprise the scale itself (discussed above) the Court should exclude Dr. Freeman's opinion that the Naranjo scale can be used to show general causation between the Lands' End uniforms and the many symptoms that Plaintiffs allege.

symptoms and complaints meet the legal standard of being causally related to their exposure to the Lands' End uniforms on a more probable than not basis." Freeman Report at 25. Currently, 276 of the 468 Plaintiffs for whom Dr. Freeman stated he could opine on specific causation remain parties to this litigation. Dr. Freeman admits that for the Plaintiffs for whom he only finds a "possible" relation, they do not satisfy the more probable than not causation standard, and more evidence is necessary for those Plaintiffs. Freeman Report at 24; Freeman Dep. at 266:17–267:8.

For the reasons explained above, even before examining his Naranjo analysis, Dr. Freeman's methodology is fatally flawed because it relies on the litigation questionnaires, which are an unreliable source of information that cannot be used to support a Naranjo analysis. *See Adams v. Procter & Gamble Distrib., LLC*, No. A1204223, 2014 WL 340129, at *4 (Ohio Ct. Com. Pl. Hamilton Cnty. Jan. 22, 2014) (citing *In re Accutane Prods. Liab.*, Nos. MDL 1626, 8:04-MD-2523-T-30TBM, 2007 U.S. Dist. Lexis 32236, at *19-20 (M.D. Fla. May 2, 2007)) ("[U]se of the Naranjo scale to validate the case reports is likewise unreliable as the scale has not been recognized by courts or scientists as a reliable method for making a determination of causation."); *Jacoby v. Rite Aid Corp.*, No. 00024, 2012 Phila. Ct. Com. Pl. LEXIS 208, at *22 (Pa. Ct. Com. Pl. Phila. Cnty June 13, 2012) ("Once again the thing from which the deduction is made is not sound. This is especially true considering most of [expert's] expert report relies upon case reports measured by the Naranjo Scale. Twenty eight reports showing a 'probable' causal association mean nothing if the case reports were collected, conducted or analyzed in a way not scientifically or methodologically sound.")

In conducting his analysis, Dr. Freeman arbitrarily assigned "points" to Plaintiffs based on their questionnaire responses. Without any valid scientific basis, Dr. Freeman assigned *all* questionnaire respondents an automatic point for question one ("Are there previous conclusive

reports on adverse health reactions to garments?"). Freeman Dep. at 251:9–21.[17] The only questions on his scale that Dr. Freeman then answered for individual Plaintiffs were questions two, three, and four. For questions two, three, and four, Dr. Freeman purported to review the questionnaires and assigned points based on individuals' responses in the questions. Freeman Dep. at 251:22–24.

Dr. Freeman employed his analysis with a thumb on the scale for finding specific causation. Specifically, for every individual for whom Dr. Freeman answered "yes" to question three ("Did the adverse event/ reaction improve once the garments were no longer worn?"), he *automatically* assigned that person a point for question six ("Did the reaction reappear when non-Lands' End garments were worn?"). Dr. Freeman achieved this result by modifying questions three and six from the original Naranjo scale in such a way that they essentially became the same question, even though in the original scale they require separate analysis. To be clear, Dr. Freeman adjusted his scale (without any apparent valid scientific basis for doing so) in a way that could only increase the likelihood of finding specific causation, as he eventually admitted:

> "Q. And what you're saying is that essentially question six is the same as question three, right?
>
> A. Well, if you meet question three then you basically said -- it's -- so it's not like a drug where you can take the drug and then you can take a placebo, it -- which is the clinical trial aspect of it or you cannot take a placebo or the drug. So either you wore the Lands' End clothing and said that it caused you to have reaction and then you stopped wearing the Lands' End clothing because you were wearing non-Lands' End clothing because as we said -- you know, you don't go to work without any clothes on, then you have essentially accomplished a placebo control.

[17] Again, Dr. Freeman's "modified" Naranjo scale does nothing to account for different Plaintiffs claiming different symptoms from different garment items, but instead treats all Plaintiffs suffering from any symptom and from any garment item as being one and the same.

> Q. So in the adverse drug reaction context where the Naranjo scale was originally developed, somebody could get a yes to question three. You could get a different outcome on question three and question six, right?
>
> A. Right. You might only get the drug and never have an opportunity and get better when you go off the drug but never have an opportunity to find out when you have the reaction when you go on a placebo.
>
> Q. So in that context if you take questions three and six together in the original use of the Naranjo scale an individual person could get zero points, one point or two points, right?
>
> A. On which –
>
> Q. On -- if you take questions three and six together.
>
> A. Yes. That's -- yes. That's true.
>
> Q. But the way in which you've adapted the Naranjo scale to this case if you take questions three and six together you get either zero points or two points, right?
>
> A. Exactly. Sorry. That was confusing."

Freeman Dep. at 259:4–260:25.[18]

Finally, despite testifying that in doing a specific causation analysis "you have to be specific and say well, was there something else that was going on at the same time that would account for this particular reaction[,]" Freeman. Dep. at 55:13–17, Dr. Freeman did not address

[18] It bears correcting, though, that on the original Naranjo scale, for questions three and six combined, an individual could actually receive a total score of -1, 0, 1, or 2 points. This is because the possible points associated with question six are -1 for a "yes" answer, 0 for "do not know," and 1 for "no." Dr. Freeman's scale, however, seems to completely disregard the possibility of a negative score. In other words, by Dr. Freeman's scale, a "yes" to question three is assigned one point, and automatically results in a "no" to question six, giving two points. But according to Dr. Freeman's scale, a "no" to question three *does not* lead to a "yes" to question six. If it did, the total would be negative one, not zero. Rather, in the instances in which Dr. Freeman determined someone should receive a "no" answer to question three, he then determined the answer for question six to be "do not know," to assign that person a zero and a higher point total, rather than negative one.

alternative causes in his specific causation analysis. Freeman Dep. at 254:19–25 ("Q. . . . so 5 through 10,[19] no individual got any points because from an individual perspective you couldn't answer any of those questions, right? A. That's correct."). As discussed above, the failure to assess alternative causes is fatal to Dr. Freeman's opinion. *Brown*, 765 F.3d at 774 ("The failure to rule out obvious potential alternative causes is therefore fatal to [expert's] testimony.")

To put it bluntly, Dr. Freeman's Naranjo-specific causation assessment is junk science—there is ample reason to question the "soundness and care" with which he arrived at his causation opinions. *Schultz*, 721 F.3d at 431 ("Although [the *Daubert* analysis] places the judge in the role of gatekeeper for expert testimony, the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion."). There is nothing scientific or methodologically sound in his Naranjo analysis. Dr. Freeman created his own scale, applied it to an area to which the Naranjo scale has no verified use, used unreliable data for his assessment, selectively decided which questions to answer on his scale, ignored questions 5, 7, 8, 9, and 10, and determined question 6 was duplicative of question 3, but *only* when it would lead to an extra point in favor of finding specific causation. There are no grounds on which Dr. Freeman can support his Naranjo analysis.[20]

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[19] Had Dr. Freeman actually considered all ten questions, he also could have assigned negative one point if the answer to question 5 (potential alternative causes) was "yes," thus further reducing the likelihood of finding probable causation.

[20] Even after all of Dr. Freeman's tortured reasoning, which is transparently designed to conclude that as many Plaintiffs as possible scored as high as possible on his "modified" Naranjo scale, he *still* only reaches a "probable" causal relationship for 276 of the remaining 603 Plaintiffs. *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1049 n.5 (S.D. Ill. 2001) ("Justifying a conclusion after the fact by applying a methodology does not generally lead to reliable scientific knowledge.").

C. Dr. Freeman is a Professional Witness Who Lacks the Necessary Expertise in Textiles and Toxicology to Opine on this Matter.

It is clear why Dr. Freeman's methodology is so wanting: Dr. Freeman is an "expert for hire" who lacks the necessary expertise to opine in this case. Before an expert is allowed to testify, the district court "must determine whether the expert is qualified in the relevant field." *Zelinski v. Columbia 300, Inc*., 335 F.3d 633, 640 (7th Cir. 2003). While Dr. Freeman may have an advanced degree in epidemiology, he does not have the needed experience in textiles or environmental toxicology to opine on causation (general or specific) in this matter. Further, how often Dr. Freeman actually *studies* epidemiology must be questioned, as the vast majority of Dr. Freeman's time is spent working as an expert for hire: he spends 70 percent of his time and derives 85 percent of his annual income from his expert witness and consulting work. *See* Freeman Dep. at 35:15–36:3. As this Court has noted, "[g]enerally, expertise comes from training and experience, not from testifying in court." *Estate of Robinson ex rel. Irwin v. City of Madison*, No. 15-cv-502-jdp, 2017 WL 564682, at *9 (W.D. Wis. Feb. 13, 2017).

Courts assessing the admissibility of testimony from experts with similarly deficient qualifications have held that such testimony does not meet the high bar set by *Daubert*. *See, e.g.*, *Muzzey v. Kerr-McGee Chem. Corp*., 921 F. Supp. 511, 514 (N.D. Ill. 1996) (excluding expert who had conducted no research and published no studies on plaintiff's alleged disease, had treated no patients with that disease, was admittedly not an expert in the medical specialty encompassing the disease, and had never been asked to provide an expert opinion on the disease outside litigation); *see also Ancho v. Pentek Corp*., 157 F.3d 512, 518–19 (7th Cir. 1998) (affirming expert's exclusion on qualifications grounds because expert did not possess sufficient knowledge to render relevant opinion).

Moreover, experts who are merely "professional witnesses" like Dr. Freeman have no place in the federal courtroom. *See, e.g.*, *Johnson v. Manitowoc Boom Trucks, Inc*., 406 F. Supp. 2d 852, 866 (M.D. Tenn. 2005) (finding expert's opinions unreliable because they were prepared entirely for litigation and therefore lacked "any indicia of reliability."), *aff'd*, 484 F.3d 426 (6th Cir. 2007); *In re Rezulin Prods. Liab. Litig*., 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004) (criticizing experts who "lend their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue"); *Newton v. Roche Labs., Inc*., 243 F. Supp. 2d 672, 679 (W.D. Tex. 2002) (disfavoring "expert[s] for hire" because their opinions are "more likely to be biased"). Accordingly, because of the substantial gaps in Dr. Freeman's qualifications regarding the issues to which he seeks to testify, his blatant disregard of epidemiological principles, and because he spends more time than not lending out his "expertise" rather than developing it, his testimony should be excluded under *Daubert*. *See Daubert, v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("[A] scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.").

V. CONCLUSION

For the reasons stated above, Lands' End respectfully requests that the Court grant this Motion and exclude all expert testimony and opinions from Dr. Michael Freeman.

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Respectfully submitted,

LATHAM & WATKINS LLP

By: s/ U. Gwyn Williams

U. Gwyn Williams (*pro hac vice*)
Samuel A. Townsend (*pro hac vice*)
Avery E. Borreliz (*pro hac vice*)
200 Clarendon Street
Boston, Massachusetts 02116
Telephone: 617.948.6000
Facsimile: 617.948.6001
gwyn.williams@lw.com
samuel.townsend@lw.com
avery.borreliz@lw.com

Attorneys for Defendant
Lands' End, Inc.